

**Remarks**

Applicants note with appreciation the Examiner's entrance of the request for continued examination under 37 C.F.R. 1.114, and the resulting withdrawal of the previous Office Action. Applicants further note with appreciation the Examiner's indication of allowance of Claims 16, 18-20, 22, 23 and 25. Applicants also appreciate the Examiner's withdrawal from rejection of Claims 13, 15, 16, 18 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Franks and Lieb in view of Fink. Lastly, the Applicants greatly appreciate the Examiner's withdrawal of the rejection of Claims 13, 14, 22 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Franks and Lieb in view of Duprat et al.

**Claim Rejection Under 35 U.S.C. § 112**

Claims 13-15 have been rejected under 35 U.S.C. § 112, first paragraph, as not being fully enabled. Applicants respectfully submit that in view of the claim amendments and in further view of the remarks set forth below the rejection is now obviated.

Applicants respectfully submit that in light of the detailed teachings of the Specification and in further view of what is well known by those skilled in the art, undue experimentation is not required for the clearly delineated Claim 13. Applicants have amended the claim in accordance with the Examiner's helpful suggestion to include SEQ ID. No. 2, 4 and 5.

Method Claim 13 is drawn to the identification of substances having anesthetic properties wherein an anesthetic is contacted with a TREK-1 or TASK mammalian potassium transport protein and wherein the TREK-1 or TASK protein exhibits outward-going potassium rectification for the subsequent determination of potassium transport activity. Applicants respectfully submit that TREK-1 and TASK have unique structural features, which make them

readily identifiable. TREK-1 or TASK proteins exhibit **outward**-going potassium rectification, and as a result are used for identifying substances having anesthetic properties. Therefore, a number of TREK or TASK mammalian proteins which are at least 95% identical to SEQ ID. No. 2, 4 or 5 could be tested to fit within the bounds of this claim.

The Applicants disclose a method for identifying substances having anesthetic properties, the method comprising the steps of contacting the substance with a TREK-1 or TASK mammalian potassium protein wherein the TREK-1 or TASK protein exhibits outward-going potassium rectification and subsequently determining the potassium transport activity of the TREK-1 or TASK protein, wherein potassium transport indicates a substance that has anesthetic properties. Applicants respectfully submit that in view of the sequences which Applicants have identified, and the knowledge concerning mammalian transport proteins, that the claims are fully supported.

The Examiner is asked to consider Example 14 of the revised interim written description guidelines training materials (copy enclosed herewith), which provided an exemplary claim drawn to a protein having a SEQ ID No and variants thereof that are at least 95% identical to that SEQ ID No. The claim described in the example combines a protein function, along with sequence parameters. The Applicant has also disclosed a claim based on a protein having a particular function, namely TREK-1 and TASK exhibit outward going potassium rectification, along with sequence parameters identical to those discussed in Example 14. Support for the use of "95% identical" to SEQ ID. No 2, 4 and 5, is found on pages 9-14 of the specification.

As a result of the specific guidelines described in Example 14, the Applicants respectfully submit that the Claims are in a condition for allowance, which action is respectfully requested.

Respectfully submitted,



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## **SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION**

### **GUIDELINES**

It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that the examiner has identified which features of the claimed invention are conventional taking into account the body of existing prior art. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. If the examiner determines that the application does not comply with the written description requirement, the examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. It should also be noted that the test for an adequate written description is separate and distinct from the test under the enablement criteria of 35 U.S.C. § 112 first paragraph. The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

The following examples only describe how to determine whether the written description requirement of 35 U.S.C. 112, para. 1 is satisfied. Regardless of

the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of Title 35 of the U.S. Code. Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

### **Example 14: Product by Function**

**Specification:** The specification exemplifies a protein isolated from liver that catalyzes the reaction of A → B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

### **Claim:**

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A → B.

### **Analysis:**

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that "having" is open language, equivalent to "comprising".

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

**Conclusion:** The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.